

REMARKS

Claims 1-23 constitute the pending claims in the present application. Claims 10-15 are withdrawn from consideration, claims 16-18 and 20-22 have been canceled, without prejudice, and claims 1, 6, 9 and 23 have been amended. The claim amendments are fully supported by the specification. No new matter has been introduced. In particular, support for the amendment to claim 1 can be found, for example, in claim 16 as originally pending; support for the amendment to claim 6 can be found, for example, at page 19, lines 1-10; and support for the amendment to claim 23 can be found, for example, at page 10, line 26 to page 11, line 2.

Additionally, the first paragraph of the specification has been amended to update the status of the parent application and to insert the filing date of one of the priority documents. The specification has also been amended to correct the European Collection of Cell Cultures (ECACC) Accession Number for monoclonal AZN-1. The ECACC deposit receipts for monoclonals AZN-1 and AZN-2 are attached hereto as Exhibits 1 and 2, respectively. Finally, the specification has been amended to reflect that SEQ ID NO: 2 is identical to the sequence set forth in Curtis et al. as noted by the Examiner in copending Application No. 10/625,204.

Amendment or cancellation of claims should in no way be construed as an acquiescence to any of the Examiner's rejections. The amendments to the claims are being made solely to expedite prosecution of the present application and do not, and are not intended to, narrow the claims in anyway. Applicants reserve the option to further prosecute the same or similar claims in the instant or in a subsequent patent application.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

Priority

As requested by the Examiner, the first line of the specification has been updated to reflect the current status of the parent application.

The Examiner alleges that the effective priority date of claims 17, 18, 21, and 22 is July 23, 2003, the filing date of the present application. The Examiner contends that "[t]here is no

support for the limitations of at least 80% and at least 90% homologous in the parent application." Applicants respectfully disagree and assert that claims 17, 18, 21 and 22 are entitled to their earliest priority date of April 19, 1999. In particular, Applicants direct the Examiner's attention to page 17, lines 21-23 of each of Applicants' priority documents, e.g., PCT Publication No. WO 00/63251 (e.g., the publication of Applicants' priority document, International Application No. PCT/NL00/00253, filed April 19, 2000), U.S. Provisional Application No. 60/176,924, filed January 20, 2000, and EP Application No. 99201204.7, filed April 19, 1999. Each of these documents state: "[s]uch variants will usually have a high degree of amino acid homology (more than 80% to more than 90%) with, and/or be functionally equivalent to the specific C-type lectin disclosed herein." Should the Examiner require copies of any of these priority documents, Applicants will be happy to provide them. Therefore, Applicants' priority documents clearly provide sufficient support for claims 17, 18, 21 and 22 and these claims are therefore entitled to the priority date of April 19, 1999. Applicants further note that claims 17, 18, 21 and 22 have been cancelled merely for purposes of expediting prosecution of the instant application.

Claim Rejections Under 35 U.S.C. §112, First Paragraph - Enablement

Claims 1-9, 17-19, 21, and 22 were rejected under 35 U.S.C. §112, first paragraph, for purposes of enablement. The Examiner states that "the specification, while being enabling for inhibiting the interaction of a C-type lectin on a dendritic cell in vitro wherein the lectin is SEQ ID #2 and the antibody binds to SEQ ID NO:2, does not reasonably provide enablement for 80% or 90% or more identity of the lectin or of antibodies that bind to the lectin." The rejection is respectfully traversed.

Applicants respectfully disagree with the rejection. However, in an effort to expedite prosecution of the application, the claims have been amended and the amendments are believed to obviate the rejection. In particular, claim 1 has been amended to refer to a protein with the amino acid sequence of SEQ ID NO: 2. Claims 2-9 and 19 are dependent on claim 1 and claims 17-18 and 21-22 have been canceled, without prejudice. The claims, as currently pending are clearly enabled by the specification. The application teaches that SEQ ID NO: 2, referred to as DC-SIGN, is expressed on the surface of dendritic cells and describes the physiological role of

dendritic cells in the immune system and how DC-SIGN, as a cell surface protein on dendritic cells, is involved in the immune response (see e.g., page 4, line 25 to page 5, line 26). In particular, the application teaches that dendritic cells present antigen to naive T cells, initiating antigen-specific primary T cell responses (see e.g., page 4, lines 25-28). The application demonstrates that the interaction between dendritic cells and T cells is mediated by an interaction between DC-SIGN on the surface of the dendritic cells and an ICAM receptor on the surface of the T cells. It is thus possible to modulate an immune response by modulating this dendritic cell-T-cell interaction. For example, a compound that binds to DC-SIGN can interfere with the interaction between DC-SIGN and an ICAM receptor, thereby inhibiting the interaction between dendritic cells and T cells, leading to a reduction in the immune response arising from this interaction (see e.g., page 5, lines 27-30, and page 6, line 25 to page 7, line 15). Compounds that bind to DC-SIGN can also be used to generate, increase or promote an immune response (see e.g., page 15, lines 3-20). Furthermore, the specification teaches a wide variety of compounds that bind to DC-SIGN and can be used to modulate an immune response (see e.g., page 8, line 25 to page 9, line 10) as well as methods for making such compounds (see e.g., page 9, line 26 to page 13, line 11), and suitable pharmaceutical compositions for such compounds (see e.g., page 13, line 26 to page 14, line 10). The specification also teaches a variety of applications of immunomodulation using the instant methods including, for example, preventing or inhibiting immune responses to specific antigens, inducing tolerance, immunotherapy, immunosuppression (e.g., to prevent transplant rejection), treatment of auto-immune diseases such as thyroiditis, rheumatoid arthritis, systemic lupus erythematosus, multiple sclerosis and auto-immune diabetes, and the prevention or treatment of allergies (see e.g., page 7, lines 16-21, and page 14, lines 21-22). Additionally, the application provides a variety of working examples. For example, the Application demonstrates that DC-SIGN mediates the interaction between dendritic cells and ICAM-3 (see e.g., Example 1, page 19, line 13 to page 20, line 21) and that antibodies to DC-SIGN block adhesion of dendritic cells to ICAM-3 (see e.g., Example 2, page 21, lines 3-6). Figure 6D shows that the DC-SIGN-ICAM-3 interaction is important in dendritic cell induced T-cell proliferation and that anti-DC-SIGN antibodies can inhibit this T cell proliferation (see e.g., Example 6, at page 27, lines 10-16; Example 7, page 28, lines 5-14). Accordingly, the application clearly provides extensive details and working examples that enable one of ordinary skill in the art to practice the methods of the claims as currently pending.

For the reasons presented above, Applicants submit that the claims fully comply with the written description requirement under 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim Rejections Under 35 U.S.C. §102

Claims 1-9 and 16-18 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Curtis (WO93/01820). The Examiner states that "Curtis discloses a compound that inhibits the interaction of the receptor" and thus concludes that Curtis anticipates the claims. Applicants respectfully traverse the rejection.

Applicants note that the claims of the instant application are directed to *methods* for *modulating an immune response* and such claims clearly are not anticipated by Curtis. In particular, Curtis is directed to the identification of a gp120 receptor which is involved in mediating HIV infection and methods for inhibiting HIV infection of mammalian cells using a compound that can inhibit the binding of the gp120 receptor to HIV (see e.g., page 8, lines 27-30). Curtis fails to teach or suggest any methods beyond inhibition of HIV infection and clearly never suggests methods for *modulating an immune response*, including, for example, methods for inducing tolerance, immunotherapy, inducing immunosuppression, treating an autoimmune disease or treating an allergy. Therefore, Curtis fails to anticipate the instant claims.

A claim is anticipated only if each and every element of the claim is found in a single prior art reference. The Curtis reference does not teach each and every element of claims 1-9 and 16-18 in the present application. Therefore, reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. §102(b) is respectfully requested.

Claims 1, 17, 18, 21 and 22 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Olson et al (US 20030232745A1). The rejection is respectfully traversed. In particular, Applicants submit that all of the claims, including claims 1, 17, 18, 21 and 22, are entitled to Applicants' earliest priority date of April 19, 1999 as discussed further above. As such, Olson, which lists an earliest possible priority date of June 26, 2001, does not qualify as prior art against the instant application under 35 U.S.C. §102. Furthermore, claims 17, 18, 21

and 22 have been cancelled thereby rendering moot the rejection as to those claims. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e) is respectfully requested.

Double Patenting

Claims 1, 3, 4, 9, and 16-23 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-3, 8, and 15-23 of copending Application No. 10/625,204.

Applicants request that the Examiner hold the provisional rejections made under the judicially created doctrine of obviousness-type double patenting in abeyance until otherwise allowable subject matter is identified in the instant application. Once allowable subject matter has been identified, Applicants will evaluate the filing of a terminal disclaimer or providing arguments in view of the claims pending at that time.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should any further extensions of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**, under Order No. ALXN-P02-089.

Dated: March 16, 2006

Respectfully submitted,

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**Centre for Applied Microbiology and Research
&
European Collection of Cell Cultures**

This document certifies that Cell Culture
(Deposit Ref. 99040818) has been accepted as a patent deposit,
in accordance with
The Budapest Treaty of 1977,
with the European Collection of Cell Cultures on 8TH April 1999

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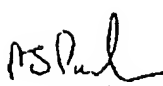
EXHIBIT 1



**Centre for Applied Microbiology and Research
&
European Collection of Cell Cultures**

This document certifies that Cell Culture
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in accordance with
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